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When Is Aortic Regurgitation Important In Transcatheter Aortic Valve Implantation

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Background: We hypothesized worsening of AR post TAVI may be more detrimental on survival than the severity of AR alone.
Methods: The CoreValve ANZ Study is currently enrolling patients with AS at 10 centers in Australia and New Zealand. AR was reported as none (N), trace (Tr), mild (Mild), moderate (Mod), severe (Sev). N/Tr AR patients were combined since TAVI studies commonly report them together. Mod/Sev patients were combined due to small samples. We assessed change in AR comparing discharge with baseline echo, and grouped patients as Unchanged/Improved (UC/Imp-AR) or Worsened (Worse-AR). Primary endpoint was all-cause mortality at 2 years.
Results: Overall baseline characteristics include; mean age of 84±6 years, 55.4% male, a mean logistic EuroSCORE 17%±10.8%, STS risk of 5.8±4.0%, mean AVA 0.7 cm2; mean gradient 50.8 ± 15.4 mmHg, and mean LVEF 58.3%±12.0%. Patients with Worse-AR at discharge were more likely men and had a lower EuroSCORE than patients with UC/Imp-AR. The severity of AR at discharge had a significant impact on survival (N/Tr, 84.6%; Mild, 78.2%; Mod/Sev, 70.9%; p=0.02) with pairwise comparison showing a significant survival benefit for patients with N/Tr vs Mod/Sev AR (p=0.005). For 355 patients (UC/Imp-AR [n=223], Worse-AR [n=132]) with paired AR data at baseline and discharge; UC/Imp-AR at discharge was associated with the best survival (UC/Imp-AR, 83.5%; Worse-AR, 72.9%; p=0.03). When combined, worsening and severity of discharge AR influenced survival (UC/Imp to None/Tr/Mild 83.7%; UC/Imp to Mod/Sev, 78.8%; Worse to Tr/Mild, 75.0%; Worse to Mod/Sev, 69.7% p=0.07). Pairwise comparisons showed the best survival in patients with UC/Imp-AR to None/Tr/Mild compared with Worse-AR to Mod/Sev, p=0.007.
Conclusions: Severity and worsening of AR affected long-term survival. Survival was most affected when AR worsened from baseline resulting in moderate/severe AR at discharge. Final mild AR may have an influence on late mortality especially if worsened from baseline. These findings will help on the decision making of the final AR especially when we expand the indications in the future to an intermediate risk cohort.

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Transcatheter aortic valve implantation via the right common carotid artery- An alternative approach

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Background: Transcatheter aortic valve implantation (TAVI) is considered in patients with severe aortic stenosis who are not suitable or high risk for open surgery. Access via the femoral approach is not feasible in people with extensive iliac and femoral vascular disease and in these patients alternative routes of access – trans-apical, subclavian or direct aortic are considered. We describe our early experience of a novel approach for TAVI via the right common carotid artery.
Methods: We present a retrospective report of seven patients in whom access for TAVI was precluded via both the femoral and subclavian arteries. A right common carotid approach was successfully utilised in these patients.
Results: Seven patients underwent TAVI with CoreValve Revalving System© via the carotid approach between August 2011 and April 2012. All these patients were deemed unsuitable for the standard trans-femoral, subclavian or direct aortic approaches. Mean age was 82 years. Procedure times ranged from 95-185 minutes. Patients demographics are shown in Table 1. There were no peri-procedural neurological complications and mortality. Non of the patients required permanent pacemaker implantation. One patient died on day 20 post-discharge related to haemopericardium related to valve implantation.

Patient number	Age	Gender	Euro score	Prev CABG	Prev MI	EF < 40%	Renal Impairment
1	84	Female	16	yes	no	no	no
2	75	male	10	no	yes	yes	no
3	71	female	10	yes	no	no	no
4	85	female	12	no	no	no	yes
5	85	female	15	no	no	no	yes
6	89	female	15	no	no	no	no
7	89	female	9	no	no	no	yes

Conclusions: In this small series, the right common carotid route has been demonstrated to be a feasible and safe access route for TAVI. It may represent a viable and novel alternative to the femoral approach with the potential to expand the patient group benefiting from this technology.

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BLEEDING AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION ACCORDING TO DIFFERENT ENDPOINT DEFINITIONS AND IMPACT ON CLINICAL OUTCOMES

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Background: Although transcatheter aortic valve implantation (TAVI) is considered less invasive compared to surgical aortic valve replacement, potential life-threatening complications may occur. Bleeding complications are frequent and well respected, as they might be associated with significant impact on clinical outcomes. We investigated the association between in-hospital bleeding events after TAVI using different definitions and their respective impact on clinical outcomes.
Methods: Between August 2007 and April 2012, a total of 489 consecutive patients with symptomatic severe aortic stenosis undergoing TAVI using different access routes and devices were included into a prospective registry. Serious adverse events were prospectively assessed and adjudicated according to standardized endpoint definitions. Bleeding complications were adjudicated according to VARC 2 and for the purpose of this analysis using the definitions of BARC, TIMI and GUSTO.
Results: Bleeding after TAVI was observed in 152 patients (31.1%) during the index hospitalization and was mainly related to access site injury (66.4%). Life threatening bleeding according to VARC 2 was associated with a significant increase in mortality at 30 days (HR 4.66, 95%CI 2.07-10.49) and 12 months of follow-up (HR 2.05, 95% CI 1.17-3.57) as was BARC bleeding≥3 (HR 3.48, 95%CI 1.66-7.30 and HR 1.62, 95%CI 1.01-2.59, respectively), TIMI major (HR 4.52, 95%CI 1.96-10.46 and HR 2.05, 95%CI 1.16-3.62, respectively) and GUSTO severe or life-threatening bleeding (HR 13.12, 95%CI 5.29-32.55 and HR 4.66, 95%CI 2.22-9.79, respectively).
Conclusions: Bleeding after TAVI was associated with a negative impact on outcomes up to 12 months of follow-up, irrespective of bleeding definition. The prognostic impact of bleeding according to the VARC 2 criteria was comparable with other well–established bleeding definitions.

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TRANSAPICAL TRANSCATHETER AORTIC VALVE IMPLANTATION WITHOUT PRIOR BALLOON AORTIC VALVULOPLASTY – FEASIBLE AND SAFE

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Background: Currently, pre-implant balloon aortic valvuloplasty (BAV) is considered a prerequisite for successful subsequent transapical transcatheter aortic valve implantation (TA-AVI) using balloon-expandable devices. However, cerebral embolization has been shown to originate at least in part from BAV procedures. Omitting BAV may therefore reduce neurologic events after TAVI and facilitate the procedure while yielding non-inferior hemodynamic and clinical outcomes.
Methods: From May, 2011 through December, 2012 a total of 50 consecutive patients were treated by TA-AVI without pre-implant BAV (TA-AVI-BAV) using the Edwards Sapien XT device (54% male, age 77.7±8.4 years, log EuroSCORE I 20.5±14.0%). Data were prospectively entered into a dedicated database, retrospectively analyzed and compared to a consecutive series of conventional TA-AVI using the same device (control group, n=50).
Results: Overall device success rate was 92% (46/50) and 90% (45/50) in TA-AVI-BAV and control groups respectively. Procedure time was similar in the TA-AVI-BAV group compared to the control group (88.2±30.8 vs. 91.1±24.5 min, p=0.60), while significantly less contrast was used (137.6±67.8 vs. 182.9±78.1 ml, p<0.001). Postprocedural peak and mean transvalvular gradients were 16.0±6.6 and 7.9±3.3 mmHg respectively in the TA-AVI-BAV group with similar values in the control group (18.7±8.5 and 9.3±4.7 mmHg, p=0.08 and p=0.09 respectively). Residual paravalvular leakage > grade 2 was present in 2% and 8% in TA-AVI-BAV and control groups respectively (p=0.36). Rates of 30-day mortality and periprocedural stroke were 6% and 10% (p=0.72) and 2% and 6% (p=0.62) respectively.
Conclusions: TA-AVI-BAV is feasible and safe and has become our default technique for patients allocated to TA-AVI with balloon-expandable devices. This approach resulted in less contrast agent used and facilitated the procedure without compromising valve performance. Effects of TA-AVI-BAV on the incidence of cerebrovascular events, other periprocedural complications or hemodynamic valve performance need to be verified in larger patient numbers before general recommendations can be made.